REMARKS

Claims 1-17 and 21-26 are pending in the present application. Please note that the multiple dependency in claim 3 has been removed as amended in the Preliminary Amendment filed on August 17, 2001, but which amendment was not reflected in subsequent submissions.

Applicants respectfully request reconsideration and allowance of the claims, in view of the remarks below. **Prior to issuance of a final Office Action, the undersigned respectfully requests a telephonic interview with the Examiner.**

Rejections Under 35 U.S.C. § 102

Claims 1-5, 7-10, and 13 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Okihara *et al.* (J. Macromol. Sci. Phys. (1991) B30 (1 & 2) 119-140). Again, the Office insists that the mixture described in Okihara "inherently forms hydrogel." (Office Action, page 2). Applicants respectfully disagree.

In *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991), the Court said: "To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be recognized by persons of ordinary skill." Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *See In re Oelrich*, 666 F.2d 578, 581 (C.C.P.A. 1981).

Contrary to the Examiner's assertions, the mixture described in the Okihara reference does not inherently form a hydrogel because the mixture contains no water. As persons of ordinary skill would recognize, a hydrogel refers to "[t]he formation of a colloid in which the disperse phase (colloid) has combined with the continuous phase (water) to produce a jellylike product." (McGraw-Hill Dictionary of Scientific and Technical Terms, Fifth Edition, p. 969, Parker S. (editor

in chief), attached as Exhibit 1, emphasis added). Furthermore, as indicated in the Hennink Declaration (Declaration Under 37 C.F.R. § 1.132, copy attached in Exhibit 2 for your convenience), it is impossible to form a hydrogel in the absence of water.

Unlike the invention as claimed, the mixtures described in the Okihara reference for preparing a stereocomplex contains no water. Rather, a few drops of a 1 % solution of PLLA in p-xylene was heated to form a polymer melt after evaporation of solvent. To prepare a stereocomplex, uniaxial-drawn films were made by melting the polymer using an equimolar mixed solution of PLLA and PDLA. (See, Okihara *et al.*, J. Macromol. Sci.-Phys. B30:119-140 (1991) at pages 120-121). Thus, even if the polymers that make up the mixtures described in the Okihara reference overlap with the polymers recited in the dependent claims, the stereocomplex of Okihara cannot form a hydrogel in the absence of water. Because the stereocomplex of Okihara cannot form a hydrogel in the absence of water, the Okihara stereocomplex are not hydrogels, whether or not the Okihara stereocomplex is capable of absorbing water.

Because the Okihara reference does not teach the hydrogels of the invention as claimed, the claims are not anticipated. Applicants therefore, respectfully request that this rejection be withdrawn.

Claims 1-10, 14, and 21-26 were also rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Hennink *et al.* (WO 98/00170). In particular, the Office indicates that Hennink discloses a hydrogel consisting of two interpenetrating polymer networks interconnecting to one another through hydrolysable spacers such as (poly)glycolic acid and/or (poly)lactic acid spacers. Thus, the teachings of Hennink allegedly meet the limitations of the claims. Applicants respectfully disagree.

Contrary to the assertions of the Office, the teachings of WO 98/00170 does not meet the limitations of the claims, which require two types of polymers, each having a chiral substituent that is complementary to the other. (See, Hennink Declaration at ¶ 9). In particular, the invention as claimed requires that the complementary chiral groups on the polymers interact noncovalently. By

definition, a chiral molecule exhibits optical activity and is not superimposable on its mirror image. The two non-superimposable mirror-image forms of chiral molecules are referred to as enantiomers. (See http://en.wikipedia.org/wiki/Chirality_(chemistry), attached at Exhibit 3). Unlike the invention as claimed, the only reference made to a chiral lactide in WO 98/00170 is in Example 3, which describes the synthesis of dex-lactate-HEMA by coupling L-lactide and HEMA thereby forming HEMA-lactate, and coupling the HEMA-lactate to dextran. Thus, WO 98/00170 fails to teach mixtures substituted with complementary chiral groups.

Furthermore, the Office had previously indicated that "Hennink's polymers encompass both isomers since no specific isomer is stated." (Advisory action mailed February 28 2005). However, when the spacer encompasses both isomers, the spacer is a racemate or a mixture of stereoisomers of a chiral molecule. Because the spacers are racemic, the mixtures are not capable of interacting noncovalently to form a hydrogel due to the absence of complementary chiral groups on the polymers. As the Office correctly pointed out, the hydrogel in WO 98/00170 is prepared by radical polymerization of a crosslinkable group such as methacrylate, forming a covalent bond between the mixtures. However, hydrogels formed by radical polymerization of a crosslinkable group contain a covalent bond between the interpenetrating polymer networks, and are distinguishable from hydrogels formed through a physical non-covalent interaction between chiral monomers of opposite chirality.

Because WO 98/00170 does not teach every element of the invention as claimed, the claims are not anticipated. Applicants therefore, respectfully request that this rejection be withdrawn.

Rejection Under 35 U.S.C. § 103

Claim 11, which depends on claim 1, was rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Hennink (WO 98/00170). Applicants respectfully disagree. As previously indicated, WO 98/00170 does not teach all the elements of claim 1. Therefore, WO 98/00170 does not render obvious claim 11, which contains all the limitations of claim 1.

Claim 12, which depends on claim 1, was rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Okihara. Applicants again respectfully disagree. As previously indicated, the Okihara reference does not teach all the limitations of claim 1. Thus, the Okihara reference does not render obvious claim 12, which contains all the limitations of claim 1.

Claims 15-17 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over De Jong *et al.* (Macromolecules (1998) 31:6397-402) in view of Brannon-Peppas (Int. J. Pharm. (1995) 116:1-9). Applicants respectfully disagree.

Contrary to the Examiner's assertions, the stereocomplexes in De Jong *et al.* (Macromolecules 31:6397-6402 (1998)) are not hydrogels. As previously indicated, it is impossible to form a hydrogel in the absence of water. Unlike the invention as claimed, the De Jong reference teaches the preparation of stereocomplexes in the absence of water. Rather, as the Office noted, polydisperse lactic acid oligomers were prepared using 2-(2-methoxyethoxy)ethanol as initiator and stannous octoate as catalyst at 130 °C until the lactide was molten. (See De Jong *et al.*, at page 6399 and 6401).

The failure to teach the preparation of a hydrogel from mixtures in an aqueous system is not remedied by the combination with Brannon-Peppas (Int. J. Pharm. 116:1-9 (1995)), which merely describes the use of biodegradable polymers in controlled drug delivery. Thus, even if De Jong and Brannon-Peppas were combined, the combination still fails to teach the process as claimed. Accordingly, claims 15-17 are nonobvious under De Jong, in view of Brannon-Peppas, and Applicants respectfully request that this rejection be withdrawn.

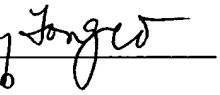
CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 313632001000. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: October 26, 2005

Respectfully submitted,

By 

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McGraw-Hill Dictionary of Scientific and Technical Terms

Fifth Edition

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of hydrogen and carbon monoxide in the presence of a cobalt catalyst. { ˌhī·drəˌfȯr·məˈlā·shən }

hydrofuge [ZOO] Of a structure, shedding water, as the hair on certain animals. { ˈhī·drəˌfyüj }

hydrogarnet [MINERAL] One of a group of minerals having the general formula $A_3B_2(SiO_4)_{3-x}(OH)_{4x}$, isomorphous with certain garnets. { ˌhī·drōˈgär·nət }

hydrogasification [CHEM ENG] A technique to manufacture synthetic pipeline gas from coal; pulverized coal is reacted with hot, raw, hydrogen-rich gas containing a substantial amount of steam at 1000 pounds per square inch gage (6.9×10^6 pascals, gage) to form methane. { ˌhī·drəˌgas·ə·fəˈkā·shən }

hydrogel [CHEM] The formation of a colloid in which the disperse phase (colloid) has combined with the continuous phase (water) to produce a viscous jellylike product; for example, coagulated silicic acid. { ˈhī·drəˌjel }

hydrogen [CHEM] The first chemical element, symbol H, in the periodic table, atomic number 1, atomic weight 1.00797; under ordinary conditions it is a colorless, odorless, tasteless gas composed of diatomic molecules, H_2; used in manufacture of ammonia and methanol, for hydrofining, for desulfurization of petroleum products, and to reduce metallic oxide ores. { ˈhī·drə·jən }

hydrogenase [BIOCHEM] Enzyme that catalyzes the oxidation of hydrogen. { hīˈdräj·əˌnās }

hydrogenated oil [ORG CHEM] Unsaturated liquid vegetable oil that has had hydrogen catalytically added so as to convert the oil to a hydrogen-saturated solid. { ˈhī·drə·jəˌnād·əd ˌȯil }

hydrogenation [CHEM ENG] Saturation of diolefin impurities in gasolines to form a stable product. [ORG CHEM] Catalytic reaction of hydrogen with other compounds, usually unsaturated; for example, unsaturated cottonseed oil is hydrogenated to form solid fats. { hīˌdräj·əˈnā·shən }

hydrogen bacteria [MICROBIO] Bacteria capable of obtaining energy from the oxidation of molecular hydrogen. { ˈhī·drə·jən bakˈtir·ē·ə }

hydrogen blistering [MET] Cracks or blisters caused when atomic hydrogen penetrates steel via submicroscopic discontinuities or voids and becomes molecular hydrogen and develops internal pressures. { ˈhī·drə·jən ˈblis·tə·riŋ }

hydrogen bomb [ORD] A device in which heavy hydrogen nuclei, under intense heat and pressure, undergo an uncontrolled, self-sustaining fusion reaction to produce an explosion. Also known as H bomb. { ˈhī·drə·jən ˈbäm }

hydrogen bond [PHYS CHEM] A type of bond formed when a hydrogen atom bonded to atom A in one molecule makes an additional bond to atom B either in the same or another molecule; the strongest hydrogen bonds are formed when A and B are highly electronegative atoms, such as fluorine, oxygen, or nitrogen. { ˈhī·drə·jən ˈbänd }

hydrogen brazing [MET] Brazing in an atmosphere rich in hydrogen. { ˈhi·drə·jən ˈbrāz·iŋ }

hydrogen bromide [INORG CHEM] HBr A hazardous, toxic gas used as a chemical intermediate and as an alkylation catalyst; forms hydrobromic acid in aqueous solution. { ˈhī·drə·jən ˈbrōˌmīd }

hydrogen-bubble method [FL MECH] A method of flow visualization in which hydrogen bubbles are generated by electrolysis of water using wire electrodes, and are made to form either time lines (by applying a pulsating voltage to a bare cathode) or streamlines (by applying a continuous voltage to a kink in an insulated cathode). { ˌhī·drə·jən ˈbəb·əl ˌmeth·əd }

hydrogen burning [ASTROPHYS] Thermonuclear reactions occurring in the cores of main-sequence stars, in which nuclei of hydrogen fuse to form helium nuclei. { ˈhī·drə·jən ˌbərn·iŋ }

hydrogen chloride [INORG CHEM] HCl A fuming, highly toxic, colorless gas soluble in water, alcohol, and ether; used in the production of vinyl chloride and alkyl chloride, and in polymerization, isomerization, and other reactions. { ˈhī·drə·jən ˈklȯrˌīd }

hydrogen cyanide *See* hydrocyanic acid. { ˈhī·drə·jən ˈsī·əˌnīd }

hydrogen cyanide laser [OPTICS] A gas laser using hydrogen cyanide, which emits infrared radiation at wavelengths of 311 and 337 micrometers. { ˈhī·drə·jən ˈsī·əˌnīd ˈlā·zər }

hydrogen cycle [CHEM] The complete process of a cation-exchange operation in which the adsorbent is used in the hydrogen or free acid form. { ˈhī·drə·jən ˌsī·kəl }

hydrogen damage [MET] Corrosion, common in boilers, caused by diffusion of hydrogen through steel reacting with carbon to form methane, which builds up local stresses at the interfaces between grains, forming voids that ultimately produce failure. { ˈhī·drə·jən ˌdam·ij }

hydrogen discharge lamp [ELECTR] A discharge lamp containing hydrogen and used as a source of ultraviolet radiation. { ˈhī·drə·jən ˈdisˌchärj ˌlamp }

hydrogen disulfide *See* hydrogen sulfide. { ˈhī·drə·jən dīˈsəlˌfīd }

hydrogen electrode [PHYS CHEM] A noble metal (such as platinum) of large surface area covered with hydrogen gas in a solution of hydrogen ion saturated with hydrogen gas; metal is used in a foil form and is welded to a wire sealed in the bottom of a hollow glass tube, which is partially filled with mercury; used as a standard electrode with a potential of zero to measure hydrogen ion activity. { ˈhī·drə·jən iˈlekˌtrōd }

hydrogen embrittlement *See* acid brittleness. { ˈhī·drə·jən em'brid·əl·mənt }

hydrogen equivalent [CHEM] The number of replaceable hydrogen atoms or hydroxyl groups in a molecule of an acid or a base. { ˈhī·drə·jən iˈkwiv·ə·lənt }

hydrogen fluoride [INORG CHEM] HF The hydride of fluoride; anhydrous HF is a mobile, colorless, liquid that fumes in air, melts at −83°C, boils at 19.8°C; used to make fluorine-containing refrigerants (such as Freon) and organic fluorocarbon compounds, as a catalyst in alkylate gasoline manufacture, as a fluorinating agent, and in preparation of hydrofluoric acid. { ˈhī·drə·jən ˈflùrˌīd }

hydrogenic ion [ATOM PHYS] An atom from which all but one of the electrons have been removed. { ˌhī·drəˈjen·ik ˈīˌän }

hydrogenic rock *See* aqueous rock. { ˈhī·drəˌjen·ik ˈräk }

hydrogen iodide [INORG CHEM] HI A water-soluble, colorless gas that may be used in organic synthesis and as a reagent. Also known as hydriodic acid gas. { ˈhī·drə·jən ˈī·əˌdīd }

hydrogen ion *See* hydronium ion. { ˈhī·drə·jən ˈīˌän }

hydrogen ion concentration [CHEM] The normality of a solution with respect to hydrogen ions, H^+; it is related to acidity measurements in most cases by $pH = \log 1/2\,[1/(H^+)]$, where (H^+) is the hydrogen ion concentration in gram equivalents per liter of solution. { ˈhī·drə·jən ˈīˌän ˌkäns·ənˌtrā·shən }

hydrogen ion exponent [CHEM] A way of expressing pH; namely, $pH = -\log c_H$, where c_H = hydrogen ion concentration. { ˈhī·drə·jən ˈīˌän ikˈspō·nənt }

hydrogen laser [OPTICS] A molecular gas laser in which hydrogen is used to generate coherent wavelengths near 0.6 micrometer in the vacuum ultraviolet region. { ˈhī·drə·jən ˈlā·zər }

hydrogen line [SPECT] A spectral line emitted by neutral hydrogen having a frequency of 1420 megahertz and a wavelength of 21 centimeters; radiation from this line is used in radio astronomy to study the amount and velocity of hydrogen in the Galaxy. { ˈhī·drə·jən ˌlīn }

hydrogen loss [MET] Loss of weight by a compact or a metal powder when heated in a hydrogen atmosphere; used as a measure of oxygen content of the sample. { ˈhī·drə·jən ˌlȯs }

hydrogen maser [PHYS] A maser in which hydrogen gas is the basis for providing an output signal with a high degree of stability and spectral purity. { ˈhī·drə·jən ˈmā·zər }

hydrogenolysis [CHEM] A reaction in which hydrogen gas causes a chemical change that is similar to the role of water in hydrolysis. { ˈhī·drə·jəˈnäl·ə·səs }

hydrogenous [CHEM] Of, pertaining to, or containing hydrogen. { hīˈdräj·ə·nəs }

hydrogen overvoltage [MET] An overvoltage occurring at an electrode as a result of the liberation of hydrogen gas. { ˈhī·drə·jən ˈō·vərˌvōl·tij }

hydrogen oxide *See* water. { ˈhī·drə·jən ˈäkˌsīd }

hydrogen peroxide [INORG CHEM] H_2O_2 Unstable, colorless, heavy liquid boiling at 158°C; soluble in water and alcohol; used as a bleach, chemical intermediate, rocket fuel, and antiseptic. Also known as peroxide. { ˈhī·drə·jən pəˈräkˌsīd }

hydrogen phosphide *See* phosphine. { ˈhī·drə·jən ˈfäsˌfīd }

hydrogen-reduced powder [MET] Metal powder produced by hydrogen-reduction of a metal, metallic compound, or surface-contaminated metal particles. { ˈhī·drə·jən riˈdüst ˈpau̇d·ər }

hydrogen selenide [INORG CHEM] H_2Se A toxic, colorless gas, soluble in water, carbon disulfide, and phosgene; used to